## THE HONORABLE RONALD B. LEIGHTON

## UNITED STATES DISTRICT COURT WESTERN DISTRICT OF WASHINGTON AT TACOMA

STORMANS, INCORPORATED, doing business as RALPH'S THRIFTWAY; RHONDA MESLER, MARGO THELEN,

Plaintiffs,

v.

MARY SELECKY, Secretary of Washington State Department of Health; et al.,

Defendants.

No. C07-5374-RBL

DEFENDANT-INTERVENORS' DAUBERT MOTION TO EXCLUDE THE TESTIMONY OF PLAINTIFFS' DESIGNATED EXPERT WITNESSES

NOTE FOR MOTION CALENDAR: July 9, 2010

DEFENDANT-INTERVENORS' *DAUBERT* MOTION (No. C07-5374-RBL) – i

#### I. INTRODUCTION

Defendant-Intervenors move the Court to exclude the opinion testimony of Plaintiffs' designated expert witnesses: Bruce M. Carlson, M.D., Ph.D.; Elizabeth Mary Shadigian, M.D.; Martha W. Shuping, M.D.; and Holly Whitcomb Henry, pursuant to Federal Rules of Evidence 402 and 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). Each of these witnesses fails to meet one or both of the fundamental requirements for expert testimony: reliability and relevancy. Their opinion testimony, therefore, should be excluded as set forth below. *Daubert*, 509 U.S. at 589; see also Kumho Tire Co. v. Carmichael, 526 U.S. 137, 147 (1999).

#### II. BACKGROUND

In 2007, the Board of Pharmacy adopted and amended two regulations—WAC 246-869-010 and WAC 246-863-095 (the "rules")—to set forth the professional responsibilities of pharmacists and pharmacies. Of relevance, the rules together require a pharmacy to ensure that patients receive lawfully prescribed medication and devices in a timely manner without discrimination. Plaintiffs contend that the rules will force them to dispense Plan B to their patients in violation of their religious beliefs. Dkt. No. 8 (Am. Compl.) ¶¶ 3-4. Plaintiffs believe that life begins with fertilization and, by potentially preventing implantation of a fertilized egg, Plan B terminates life. *Id.* Plaintiffs therefore contend that the rules are unconstitutional, asserting claims under the Free Exercise Clause, the Supremacy Clause, and the Due Process Clause of the U.S. Constitution. Dkt. No. 9 (Am. Compl.).

Plaintiffs designated Bruce M. Carlson, M.D., Ph.D.; Elizabeth Mary Shadigian, M.D.; Martha W. Shuping, M.D.; and Holly Whitcomb Henry to testify at trial as expert witnesses in their Pretrial Statement. Boeder Decl., Ex. A (Pls. Pretrial Statement). Consistent with Federal Rule of Civil Procedure 26(a)(2), Plaintiffs had previously disclosed reports setting forth the opinions and curriculum vitae of each of these potential witnesses. Boeder Decl., Exs. B, C, D,

DEFENDANT-INTERVENORS' *DAUBERT* MOTION (No. C07-5374-RBL) – 1

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E, and G (Carlson Report, Shadigian Report, Shuping Report, Henry Report, and Henry Rebuttal Report). Defendant-Intervenors deposed Ms. Henry only. Boeder Decl., Ex. F (Henry Dep.).

In accordance with the requirements of Local Civil Rule 7(d)(4), on June 23, 2010, counsel for Defendant-Intervenors conferred with counsel for Plaintiffs and the State Defendants by telephone. Boeder Decl. ¶ 9. Counsel discussed Defendant-Intervenors' objections to Plaintiffs' designated expert witnesses. *Id.* Defendant-Intervenors certify that the parties were unable to resolve Defendant-Intervenors concerns with Plaintiffs' proposed opinion testimony. *Id.* 

#### III. ARGUMENT

Each of Plaintiffs' designated expert witnesses fail to meet one or both of the basic requirements for expert testimony: reliability and relevancy. Their opinion testimony, therefore, should be excluded as set forth below.

## A. Bruce Carlson, M.D., Ph.D

Plaintiffs have designated Bruce M. Carlson, M.D., Ph.D, an embryologist, to testify regarding "the biology of the early human embryo, the basis for Plaintiffs' view from a scientific perspective that a human embryo merits protections upon fertilization, and the mechanism of action of Plan B." Boeder Decl., Ex. A (Pls. Pretrial Statement) at 8, Ex. B (Carlson Report) at 3-9. But the validity of Plaintiffs' religious belief that life begins at fertilization (and that Plan B—by supposedly preventing implantation of a fertilized egg—interferes with it) is not in question.

As a matter of law, the Court must accept those beliefs as given. Indeed, as the Ninth Circuit Court of Appeals admonished in *Callahan v. Woods*, 658 F.2d 679, 685 (9th Cir. 1981): "In applying the free exercise clause of the First Amendment, courts may not inquire into the truth, validity, or reasonableness of a claimant's religious beliefs." *See also United States v. Ballard*, 322 U.S. 78, 87 (1944) ("Man's relation to his God was made no concern of the state. He was granted the right to worship as he pleased and to answer to no man for the verity of his

DEFENDANT-INTERVENORS' *DAUBERT* MOTION (No. C07-5374-RBL) – 2

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religious views. . . . When the triers of fact undertake that task, they enter a forbidden domain."). Therefore, opinion testimony by Dr. Carlson addressing the scientific understanding of when "life" begins (and whether or not Plan B interferes with it) will not aid the Court in understanding evidence or "determining a fact in issue" as required by Federal Rule of Evidence 702. It should be excluded as irrelevant. Fed. R. Evid. 401, 402, and 702. See also United States v. Dean, 980 F.2d 1286, 1288 (9th Cir. 1992) ("For evidence to be relevant it must be probative of the proposition it is offered to prove and the proposition to be proved must be one that is of consequence to the determination of the action.") (internal quotation marks and citation omitted).

## B. Elizabeth Mary Shadigian, M.D.

Plaintiffs have designated Elizabeth Mary Shadigian, M.D., to testify regarding "the biology of the human embryo" and "the mechanism of action of Plan B." Boeder Decl., Ex. A (Pls. Pretrial Statement) at 9, Ex. C (Shadigian Report) at 3-4. Her opinion—that, as a matter of science, life begins at fertilization, and that Plan B, by potentially preventing implantation, interferes with it—is identical to that offered by Dr. Carlson. Boeder Decl., Ex. C (Shadigian Report) at 3-4. Not only does her testimony therefore violate Local Civil Rule 43(j)—which prohibits a party from calling more than one expert witness on any subject—but, as noted above, the validity of Plaintiffs' religious belief that life begins at fertilization is not in question. *See Callahan*, 658 F.2d at 685. Therefore, Dr. Shadigian's opinion testimony on the topic should also be excluded as irrelevant. Fed. R. Evid. 401, 402, and 702. *See also Dean*, 980 F.2d at 1288.

## C. Martha W. Shuping, M.D.

Plaintiffs have identified Dr. Martha Shuping as an expert witness on "the definition, prevalence, and incidence of rape in Washington [and] the risk of pregnancy from rape," as well as "the symptoms and effect of post-traumatic stress disorder and the accessibility of and alleged need for Plan B by victims of rape." Boeder Decl., Ex. A (Pls. Pretrial Statement) at 8-9. Her

DEFENDANT-INTERVENORS' *DAUBERT* MOTION (No. C07-5374-RBL) – 3

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opinion testimony is intended to rebut the testimony by Defendant-Intervenors' expert witness, Karil Klingbeil. Ms. Klingbeil is a "nationally-recognized" expert in sexual assault and domestic violence trauma, *Saldivar v. Momah*, 145 Wn. App. 365, 397, 186 P.3d 1117 (2008), and will opine that women who are sexually assaulted and seek emergency contraception may be further traumatized if a pharmacist refuses their request for the drug. In contrast to Ms. Klingbeil, Dr. Shuping lacks the qualifications necessary to provide expert testimony on this topic. In addition, some of Dr. Shuping's proposed testimony misses the mark; her opinion on the *precise* number of pregnancies resulting from rape in Washington State is not relevant.

1. Dr. Shuping's Opinions Regarding the Prevalence and Incidence of Rape and Resulting Pregnancy Is Statistically Unsupported and Not Otherwise Relevant

In a misguided effort to rebut the critical importance of timely access to Plan B to victims of sexual assault, Dr. Shuping attempts to minimize the number of women who become pregnant as a result of rape in Washington State. Boeder Decl., Ex. D (Shuping Report) at 4-6. Dr. Shuping lacks the qualifications necessary to conduct such an analysis. She is not an expert on the subject of statistical analysis. She is a psychiatrist. Publications and speaking engagements on the psychological effects of abortion comprise the vast majority of her curriculum vitae. *Id.* at 1.

Her opinion regarding the precise number of women who become pregnant as a result of rape goes well beyond simply relying on scientific studies that are accepted in the field. Rather, it requires additional manipulation of the results of those studies, *i.e.*, adding and subtracting percentages from several independent statistical studies, to ascertain with precision the number of women impregnated in Washington State annually as a result of rape—132. Boeder Decl., Ex. D (Shuping Report) at 4-6. That number has not been confirmed by any reliable experts in the field of statistical analysis. Neither the number itself, nor the underlying reasoning and methodology employed by Dr. Shuping to arrive at it, has been subject to peer-review or other verification. As such, it should be excluded. Fed. R. Evid. 702; *Daubert*, 509 U.S. at 592-93

DEFENDANT-INTERVENORS' *DAUBERT* MOTION (No. C07-5374-RBL) – 4

(expert testimony is only admissible when "the reasoning or methodology underlying the testimony is scientifically valid"); Jinro Am., Inc. v. Secure Invs., Inc., 266 F.3d 993, 1005-06 (9th Cir. 2001) (excluding expert who lacked necessary qualifications as unreliable). See also Rink v. Cheminova, Inc., 400 F.3d 1286, 1291 (11th Cir. 2005) (excluding "speculative, unreliable expert testimony").

Furthermore, regardless of reliability, the *precise* number of women impregnated in Washington State annually as a result of rape is irrelevant. That number does not have "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401; see also Dean, 980 F.2d at 1288. It should therefore be excluded. Fed. R. Evid. 402 and 702.

The only relevant facts here are that *some* women are impregnated as a result of rape and that, as a result, women who are raped face the possibility of becoming pregnant and may therefore seek emergency contraception. These facts are not in dispute. Indeed, these facts, originally proffered by Defendant-Intervenors' expert Karil Klingbeil and brought to the attention of the Board of Pharmacy during the rulemaking process by the Washington Coalition of Sexual Assault Programs, provide a rational basis for enacting the regulations at issue, *i.e.*, removing a potential barrier to emergency contraception for rape victims and preventing a possible source of further trauma for rape victims.

2. Dr. Shuping's Opinion Regarding the Impact of a Pharmacist's Refusal to Provide Emergency Contraception on Sexual Assault Victims Is Speculative

Dr. Shuping's further opinion that a sexual assault victim would not be distressed by a pharmacist's refusal to provide her with emergency contraception is pure speculation. Boeder Decl., Ex. D (Shuping Report) at 11. Dr. Shuping is not an expert in sexual assault trauma. Her lack of qualification in this subject area is apparent from her curriculum vitae; she has not researched, published an article, or spoken on the subject of sexual assault trauma. She has not conducted any research or undertaken any studies on the needs of women following sexual

DEFENDANT-INTERVENORS' *DAUBERT* MOTION (No. C07-5374-RBL) – 5

Perkins Cole LLP 1201 Third Avenue, Suite 4800 Seattle, WA 98101-3099 Phone: 206.359.8000

assault. Her opinion appears to be based—at best—on limited and anecdotal experience with some of her patients, for whom she claims pregnancy was not a "major focus of concern" following sexual assault. *Id.* at 9. That claim not only defies common sense, but also, *as she admits*, directly contradicts a scientific study on this topic. *Id.* (citing National Women's Study which concluded that 61% of women who had been recently raped were concerned about the risk of pregnancy).

Dr. Shuping also offers no basis for her conjecture that this contradiction—between her limited experience and an established scientific study—is due to broad changes in contraceptive practices. *Id.* Her opinion is based on her assumptions that any referral would be "handled in a respectful, matter of fact way with no reason for shame" and that women are used to receiving referrals at pharmacies. *Id.* at 9-10. Dr. Shuping cites no evidence—aside from her own subjective lay beliefs (she is no expert in pharmacy practice or business)—for these assumptions. Proffered experts, such as Dr. Shuping, must arrive at their conclusions using scientific methods and procedures. *Daubert*, 509 U.S. at 592-93. Conclusions based on subjective beliefs or unsupported speculation, as are Dr. Shuping's, are not admissible. *See Claar v. Burlington N. R.R. Co.*, 29 F.3d 499, 502 (9th Cir. 1994); *see also Jinro*, 266 F.3d at 1005-06 (excluding as unreliable an expert who did not cite scientific studies or methods and instead made sweeping generalizations based on anecdotal experiences).

## D. Holly Whitcomb Henry

Finally, Plaintiffs have identified Holly Whitcomb Henry as an expert witness on a number of diverse subjects, including, of relevance here, (1) the availability of Plan B in Washington State; (2) "the evolution of the Board of Pharmacy's enactment and interpretation" of the rules and the operation of the exemptions to the rules; (3) the advisability of a "refuse and refer" policy; and (4) "the ethical obligations of a pharmacist." Boeder Decl., Ex. A (Pls. Pretrial Statement) at 8. Ms. Henry is a licensed pharmacist who has practiced pharmacy for many years in Washington State and owned and operated several pharmacies. Boeder Decl., Ex. E (Henry

DEFENDANT-INTERVENORS' *DAUBERT* MOTION (No. C07-5374-RBL) – 6

Report) at 1. She has also served as an officer and a member of the Board of Directors of the Washington State Pharmacy Association, the National Community Pharmacy Association, and the Pharmacist's Mutual Insurance Company. *Id.* Finally, she serves on the faculty of two pharmaceutical schools in Washington State. *Id.* Although she may have expertise in the practice of pharmacy based on her experience, she is not qualified to testify as to the additional subjects identified by Plaintiffs. She admits as much in her deposition:

- Q. ... What do you understand the scope of your expertise as it applies to this case?
- A. My understanding of my expertise as it relates to this case is serving as an expert for standards of practice in community pharmacy practice, best practices in community pharmacy practice and also real world information about what really goes on in grass roots pharmacies. . . .

Boeder Decl., Ex. F (Henry Dep.) at 84:03-84:11. Nor are her opinions on those additional subjects necessarily relevant. As such, her testimony should be limited, at most, to her general experience in the practice of pharmacy. *Daubert*, 509 U.S. at 589; Fed. R. Evid. 402 and 702.

1. Ms. Henry's Opinions Regarding the Availability of Plan B in Washington State Are Not Supported and Are Otherwise Irrelevant

Ms. Henry intends to testify that "if a woman needs timely access to emergency contraception in the State of Washington there's almost zero percent chance that she can't access it." Boeder Decl., Ex. F (Henry Dep.) at 17:24-18:02. However, the methodology and reasoning she used to reach that conclusion is insufficient. Ms. Henry examined only the supply of Plan B in Washington State. She made no effort to inquire into any other factor that determines whether or not a woman can obtain Plan B in a timely manner. She did not consider, for example:

- That the availability of Plan B through a local Planned Parenthood clinic is irrelevant if the refusal occurs on the weekend when the clinic is closed.
- That the availability of Plan B at another pharmacy five miles away is irrelevant if the woman who is refused does not have a car or other mode of transportation.
- That the availability of Plan B at other pharmacies in the same town is irrelevant if the pharmacist refuses to provide a referral and the woman is unfamiliar with the town (e.g., from another part of the state or a recent immigrant who does not speak English).

DEFENDANT-INTERVENORS' *DAUBERT* MOTION (No. C07-5374-RBL) – 7

• That the availability of Plan B through the Internet is irrelevant if the woman does not have access to a computer. In any event, a 24-hour delay in receipt of Plan B materially reduces its effectiveness.

Similarly, her reliance on the lack of complaints to the Board of Pharmacy as evidence that access to Plan B has never been denied is unfounded. There are a multitude of factors that might explain why a woman might fail to register a complaint, including unfamiliarity with the process and a reluctance to expose her private matters (contraceptive use) to strangers. Ms. Henry does not even acknowledge these obvious explanations.

The absence of necessary rigor underlying her opinion is not surprising given her lack of any expertise in statistical or data analysis. Although she has participated in studies, providing input as a practitioner and collecting data, she has never been responsible for reaching conclusions based on the data. In her deposition, she stated:

- Q. In any of the studies that you have listed here under research experience, were you responsible for processing data and reaching conclusions based upon that data?
- A. I was responsible for processing data on a lot of the projects, but not involved with developing conclusions in most of those projects.

. . . .

- Q. Were you ever asked to perform any kind of analytical analysis over the data before submitting it to the people who were running the study?
- A. I'd say no.

Boeder Decl., Ex. F (Henry Dep.) at 55:11-56:04. See also id. at 59:01-60:10. Indeed, her knowledge of statistics is no different than any other typical pharmacist. Id. at 43:02-44:18 (describing the two statistic courses she took as an undergraduate in pharmacy). Cf. Newton v. Roche Lab., Inc., 243 F. Supp. 2d 672, 678-79 (W.D. Tex. 2002) (holding that a pharmacist did not have the qualifications to render an opinion involving pharmacology because he had only taken one pharmacology course during his training to become a pharmacist). She acknowledged her lack of expertise in this area in her deposition when she revealed that she reached her opinion

DEFENDANT-INTERVENORS' *DAUBERT* MOTION (No. C07-5374-RBL) – 8

by consulting with unidentified individuals who—in her words—have "expertise" in the area. Boeder Decl., Ex. F (Henry Dep.) at 17:01-17:20 and 91:23-92:21.

There is simply too great of an analytical gap between the data and the opinion offered by Ms. Henry. See Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146-47 (1997); Daubert, 509 U.S. at 592-93 (opinion testimony must be based on "reasoning or methodology . . . [that] is scientifically valid."); see also Fed. R. Evid. 702; Rink, 400 F.3d at 1291 (excluding "speculative, unreliable expert testimony"). Moreover, she is not qualified to make sweeping conclusions about the availability of Plan B to women—across economic and social circumstances and across the state. Her opinion on this matter should also be excluded. Fed. R. Evid. 702; LuMetta v. U.S. Robotics, Inc., 824 F.2d 768, 771 (9th Cir. 1987) (excluding expert witnesses who lacked necessary qualifications).

Second, regardless of reliability, the availability of Plan B in Washington State is irrelevant. It does not have "any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401; *see also Dean*, 980 F.2d at 1288. Even assuming that Ms. Henry is correct and Plan B is widely available, the Board of Pharmacy need not demonstrate a systemic lack of access to enact rules that prevent restriction of access.

2. Opinions Relating to the Evolution of the Board of Pharmacy's Enactment and Interpretation of the Rules and Operation of Exemptions Are Not Relevant

Ms. Henry intends to offer the opinion that the rules allow a "host of exemptions" for secular conduct such that the only conduct prohibited by the rules is a refusal to stock and dispense drugs based on a religious conviction. Boeder Decl., Ex. E (Henry Report) at 3-5. As an initial matter, this testimony is irrelevant. The Ninth Circuit has already determined, as a matter of law, that the exemptions do not single out religious conduct. It held:

• "Under the rules, all pharmacies have a 'duty to deliver' all medications 'in a timely manner.' Neither regulation challenged in this case applies to refusals only for religious

DEFENDANT-INTERVENORS' *DAUBERT* MOTION (No. C07-5374-RBL) – 9

Perkins Coie LLP 1201 Third Avenue, Suite 4800 Seattle, WA 98101-3099 Phone: 206.359.8000

reasons. The new rules apply to all lawful medications, not just those that pharmacies or pharmacists may oppose for religious reasons." *Stormans*, 586 F.3d at 1134.

- The exemptions "are a reasonable part of the regulation of pharmacy practice, and their inclusion in the statute does not undermine the general applicability of the new rules." *Id.* at 1135.
- "[T]he rules do not selectively impose an undue obligation on conduct motivated by religious belief because the rules actually provide for religious accommodation. . . ."

  Id. at 1137.

Accordingly, Ms. Henry's testimony on the enforcement of the rules should be excluded as irrelevant. *Daubert*, 509 U.S. at 591; Fed. R. Evid. 402 and 702.

Even if relevant, her testimony consists of a number of observations about the Board of Pharmacy's alleged historical enforcement of the "stocking" rule—which is not at issue here. Boeder Decl., Ex. E (Henry Report) at 3-5. Those observations are statements of fact, not an expert opinion. If there were evidence of enforcement of the stocking regulation by the Board, the finder of fact could determine the facts without help from Ms. Henry. Expert opinion testimony is appropriate only when it addresses a factual issue that the trier of fact would not ordinarily be able to resolve without technical or specialized assistance. *Daubert*, 509 U.S. at 592. To be admissible, "expert testimony . . . must address an issue beyond the common knowledge of the average layman." *United States v. Vallejo*, 237 F.3d 1008, 1019 (9th Cir. 2001). On this ground too it should be excluded.

Finally, Ms. Henry should not be permitted to testify about or make reference to the enactment of the rules. She did not disclose any opinion regarding the enactment of the rules. See Boeder Decl., Exs. E & G (Henry Report and Henry Rebuttal Report). See also Fed. R. Civ. P. 26(a)(2) (requiring a "complete statement" of "all opinions" and "the basis and reasons for them"). See also Yeti by Molly, Ltd. v. Deckers Outdoor Corp., 259 F.3d 1101, 1106 (9th

Indeed, Plaintiffs might call to testify as lay witnesses those individual pharmacists and pharmacy owners who were the subject of Board investigations with whom Ms. Henry purportedly spoke and bases her factual testimony. Or, more directly, Plaintiffs could question members and staff of the Board of Pharmacy regarding their alleged enforcement of the rules.

Cir. 2001) (district court has wide latitude to issue sanctions including exclusion of expert testimony if party fails to adhere to Rule 26).

## 3. The Advisability of Refuse and Refer Is Not Before the Court and Is Therefore Not Relevant

Ms. Henry also intends to testify regarding the feasibility and benefits of a policy that allows a pharmacist or pharmacy to "refuse and refer" (to another pharmacist or pharmacy) patients who request a medication to which they object. Boeder Decl, Ex. A (Pls. Pretrial Statement) at 8; Boeder Decl., Ex. E (Henry Report) at 6-7. But, at trial, this Court must determine only whether or not there is a rational basis in support of the rules. *Stormans*, 586 F.3d at 1137-38. Whether or not there is a better policy option is irrelevant to that inquiry. Rational basis review requires judicial deference to legislative judgment and "is not a license for courts to judge the wisdom, fairness, or logic of legislative choices". *Heller v. Doe*, 509 U.S. 312, 319 (1993) (quoting *FCC v. Beach Commc'ns, Inc.*, 508 U.S. 307, 313 (1993)). Accordingly, Ms. Henry's opinion testimony on this point should be excluded as irrelevant. Fed. R. Evid. 402 and 702.

# 4. The Ethical Obligations of Pharmacists Do Not Affect Interpretation of the Rules

Finally, Ms. Henry intends to testify that allowing a pharmacist to refuse to dispense medication based on a religious objection as well as the practice of referring customers to another pharmacist are consistent with the ethical obligations of pharmacists. Boeder Decl., Ex. G (Henry Rebuttal Report) at 1-3. This opinion testimony is intended to rebut Defendant-Intervenors' expert Alta Charo, Ph.D. Dr. Charo, a professor of law and bioethics at the University of Wisconsin at Madison, who will opine that the rules are consistent with the ethical obligation—to put the interests of the patient first—that govern the pharmacy profession.

But Ms. Henry is not an expert in biomedical ethics. In fact, she has had no formal training in biomedical ethics:

Q. Now, have you had any formal training in bio ethics?

DEFENDANT-INTERVENORS' *DAUBERT* MOTION (No. C07-5374-RBL) – 11

- A. No. Again, it was a subject that was addressed in some of my course work as an undergraduate and I've taken a continuing education seminar here or there that would address various aspects of bio ethics but nothing that I would consider to be formal training, no.
- Q. Any formal education in medical ethics?
- A. No.

Boeder Decl., Ex. F (Henry Dep.) at 47:23-48:18. Indeed, her knowledge of ethics is no different than any other pharmacist. To offer opinion testimony, a witness must be "qualified as an expert by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. *See also LuMetta*, 824 F.2d at 771 (excluding expert witnesses who lacked necessary qualifications). Ms. Henry fails to meet this test; her opinion regarding the ethical obligations of pharmacists should therefore be excluded.

#### IV. CONCLUSION

For the reasons stated above, the Court should limit or exclude altogether the proposed opinion testimony by Plaintiffs' designated expert witnesses Bruce M. Carlson, M.D., Ph.D.; Elizabeth Mary Shadigian, M.D.; Martha W. Shuping, M.D.; and Holly Whitcomb Henry pursuant to Federal Rules of Evidence 402 and 702 and *Daubert*, 509 U.S. 579.

## RESPECTFULLY SUBMITTED this 24th day of June. 2010.

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DEFENDANT-INTERVENORS' DAUBERT MOTION (No. C07-5374-RBL) – 13

#### CERTIFICATE OF SERVICE

I certify that on June 24, 2010, I electronically filed the foregoing **Defendant-Intervenors'** Daubert Motion to Exclude the Testimony of Plaintiffs' Designated Expert Witness with the Clerk of the Court using the CM/ECF system, which will send notification to all counsel of record.

I certify under penalty of perjury that the foregoing is true and correct.

DATED: June 24, 2010

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